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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,854	11/24/2003	Shozo Koyama	AMN-005-004	3661

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EXAMINER

WITHERSPOON, SIKARL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/718,854	Applicant(s) KOYAMA ET AL.	
	Examiner Sikarl A. Witherspoon	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/813,842.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant is advised that the Notice of Allowance mailed August 10, 2005 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account. The following rejections are now being made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting or blocking molecular generating and/or inducing functions of molecules by contacting said molecules with a compound of formula (3-a), specifically, 4,4-dimethyl-6-methylene-cyclohex-2-ene-1-one, or *yoshixol*, does not reasonably provide enablement for said method using any other compound or species that may be encompassed by the genus of formula (3-a). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Accordingly, the examiner purports that it would constitute undue

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experimentation to determine what compounds encompassed by the genus of formula (3-a) can be effectively employed for the method of the instant claims.

There are eight (8) factors considered by the Federal Circuit in the determination of undue experimentation, *In re Wands*, 8 USPQ2d 1400 (1988). These factors are: the nature of the invention, the breadth of the claims, the state of the prior art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples, the relative skill of those in the art, and the quantity of experimentation necessary. The examiner will discuss these factors as they apply to the instant invention.

The instant invention is drawn to the use of cyclohexenone derivatives represented by formula (3-a) in a method for inhibiting or blocking molecular generating and/or inducing functions of molecules. The independent claim is extremely broad in that the method described therein can encompass a potentially infinite number of molecular generating and/or inhibiting functions of molecules, and a potentially infinite possible compounds based on formula (3-a) can be employed in the claim method.

The use of chemical compounds to affect molecular and/or biological functions in an unpredictable endeavor from the perspective that while a certain class of compound, for example, a cyclohexenone compound, may be effective in affect one type of molecular function, a person of skill would not reasonably expect a given compound to affect all or a wide, seemingly unrelated, list or molecular functions, as is the case in the instant claims. Furthermore, while one derivative of a compound may produce a

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desired result, another derivative of the same core compound, i.e., a compound having different substituents, or different positioning of substituents, may not produce the desired affect.

The instant disclosure provides many different species of the compound represented by formula (3-a), and the specification, including the instant dependent claims, recite a myriad of molecular generating or inducing functions, many of which are seemingly unrelated, for example, from reduction to desulfurization; from to killing sperm cells to depolymerization; and from restoration of hair to improving polymerization.

From the instant specification, including the working examples, a person of ordinary skill would be able to practice the method of the instant invention, even for affecting the myriad of different processes or molecular functions claimed herein, using the compound designated, yoshixol. While the level of skill in this art is presumably high, i.e., an artisan with advanced level training would be conducting this type of experiment, there is no way that a person of skill in the art could look at the many species of the compound of formula (3-a) and ascertain which, if any of the specific species, besides yoshixol, can be employed in the method of the present invention, and produce the desired effect of inhibiting or blocking molecular generating and/or inducing function of molecules, specifically in the wide range or molecular processes or functions described in the specification and recited in the instant claims.

Without further guidance from the present disclosure, a person skill in the art would have to select a compound or species of the general formula (3-a) and, since

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many of the functions or process recited by the claims are unrelated, text said compound or species to see if the desired effect is obtained in each of the methods recited in the instant claims, and then, potentially go through testing all of the possible species, or at least those that are represented in the specification, to see if the desired effect is obtained in each of the methods recited in the claims. This amount of experimentation would be considered unduly burdensome to a person of skill in the art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47, 62 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 is indefinite as it fails to recite what molecular generating and/or inducing functions are. This can be applied to a great many molecular functions, and so it is unclear what applicants' intent is in this regard.

In claim 62, it is unclear what is being stabilized, and what is meant by improving stabilization.

In claim 67, line 3, it is unclear what the word, "pains" has to do with affecting wavelength of pigments, coating material, colorants, etc.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 47, 54 and 56 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 9, and 16 of prior U.S. Patent No. 6,346,551. This is a double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sikarl A. Witherspoon whose telephone number is 571-272-0649. The examiner can normally be reached on M-F 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Sikarl A. Witherspoon
SIKARL A. WITHERSPOON
PATENT EXAMINER